MAY - 3 2000

K000349

510(k) Summary of Safety and Effectiveness

Date: February 2, 2000

Device: Stryker Leibinger Motorized Micro Multileaf Collimator

Proprietary Name: Motorized Micro Multileaf Collimator

Common Name: Therapeutic X-Ray Collimator

Proposed Regulatory Class: II

Device Classification: IYE 892.5710

The Stryker Leibinger Motorized Micro Multileaf Collimator is a conformal radiation therapy and radiosurgery device intended to provide the delivery of a shaped X-ray beam from a radiation therapy source. The Motorized Micro Multileaf Collimator is attached to a linear accelerator and consists of a series of pairs of parallel tungsten leaves that collimate radiation delivery to a target according to a treatment plan generated by planning software such as the Stryker Leibinger Virtuoso software. The device is used to assist the clinician in delivery of well-defined target volumes of radiation while sparing the surrounding tissues and organs. The Motorized Micro Multileaf Collimator should only be used for fixed field X-ray treatments.

The Motorized Micro Multileaf Collimator conforms to the following standards:
EN 60601-1 (IEC 601-1)
EN 60601-1-1 (IEC 601-1-1)
EN 60601-1-2 (IEC 601-1-2)
EN 60601-1-4 (IEC 601-1-4)

The Motorized Micro Multileaf Collimator is substantially equivalent to several other legally marketed devices. Examples of these are:

1. Brainlab Multileaf Collimator (K970586)
2. Radionics Multileaf Collimator (K982549)

For information contact:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Kristyn R. Kelley
Project Engineer
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4100 East Milham Avenue
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Re: K000349
Motorized Micro Multileaf Collimator
Dated: February 2, 2000
Received: February 3, 2000
Regulatory class: II
21 CFR 892.5710/Procode: 90 IXI

Dear Ms. Kelley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): Unknown

Device Name: Motorized Micro Multileaf Collimator

Indications for Use:

The Stryker Leibinger Motorized Micro Multileaf Collimator is a conformal radiation therapy and radiosurgery device intended to provide the delivery of a shaped X-ray beam from a radiation therapy source. The Motorized Micro Multileaf Collimator is attached to a linear accelerator and consists of a series of pairs of parallel tungsten leaves that collimate radiation delivery to a target according to a treatment plan generated by planning software such as the Stryker Leibinger Virtuoso software. The device is used to assist the clinician in delivery of well-defined target volumes of radiation while sparing the surrounding tissues and organs. The Motorized Micro Multileaf Collimator should only be used for fixed field X-ray treatments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Carolyn Y Neuland for DRS
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000349